DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

April 14, 2015

Implanet S.A.
% Ms. Janice M. Hogan
Hogan Lovells US, LLP
1835 Market Street, 29th Floor
Philadelphia, Pennsylvania 19103

Re: K143731
Trade/Device Name: IMPLANET Spine System
Regulation Number: 21 CFR 888.3070
Regulation Name: Pedicle screw spinal system
Regulatory Class: Class III
Product Code: NKB, OSH, MNH, MNI, KWP
Dated: January 14, 2015
Received: January 14, 2015

Dear Ms. Hogan:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson -S

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement on last page

510(k) Number *(if known)*

K143731

Device Name

IMPLANET Spine System

Indications for Use *(Describe)*

The IMPLANET Spine System is intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion of the thoracic, lumbar and/or sacral spine. The IMPLANET Spine System is intended for posterior, non-cervical pedicle and non-pedicle fixation for the following indications: degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies), spondylolisthesis, trauma (i.e., fracture or dislocation), spinal stenosis, spinal deformities (i.e., scoliosis, kyphosis and/or lordlosis), tumor, pseudarthrosis, or revision of a failed fusion attempt. When used for posterior non-cervical pedicle screw fixation in pediatric patients, the IMPLANET Spine System implants are indicated as an adjunct to fusion to treat adolescent idiopathic scoliosis. These devices are to be used with autograft and/or allograft. Pediatric pedicle screw fixation is limited to a posterior approach.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) SUMMARY

Implanet S.A.'s IMPLANET Spine System

Submitter's Name, Address, Telephone Number, Contact Person and Date Prepared

Implanet S.A.
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Contact Person: Regis Le Couedic, Director of Quality and Regulatory Affairs and CTO

Date Prepared: April 10, 2015

Name of Device

IMPLANET Spine System

Common or Usual Name

Pedicle screw spinal system

Classification Name

888.3070 – Spinal Pedicle Fixation Orthosis - NKB, OSH, MNI, MNH

888.3050 – Spinal Interlaminal Fixation Orthosis - KWP

Predicate Devices

IMPLANET Spine System (K120564; K132303 (*Primary Predicate*))

Purpose of the 510(k) Notice

The IMPLANET Spine System (ISS) is a modification to the cleared IMPLANET Spine System (K120564; K132303).

Intended Use

The IMPLANET Spine System is intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion of the thoracic, lumbar and/or sacral spine. The IMPLANET Spine System is intended for posterior, non-cervical pedicle and non-pedicle fixation for the following indications: degenerative disc disease

(defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies), spondylolisthesis, trauma (i.e., fracture or dislocation), spinal stenosis, spinal deformities (i.e., scoliosis, kyphosis and/or lordlosis), tumor, pseudarthrosis, or revision of a failed fusion attempt. When used for posterior non-cervical pedicle screw fixation in pediatric patients, the IMPLANET Spine System implants are indicated as an adjunct to fusion to treat adolescent idiopathic scoliosis. These devices are to be used with autograft and/or allograft. Pediatric pedicle screw fixation is limited to a posterior approach.

Device Description

The IMPLANET Spine System is a posterior instrumentation system. The polyaxial screws are made of Ti6Al4V titanium alloy compliant with ISO 5832-3. The polyaxial screw is comprised of three sections: the pedicle screw; the head; and a ring that connects the screw to the head. The polyaxial screws are offered in diameters ranging from 5.0 to 7.5 mm and in lengths ranging from 35 to 60 mm.

The monoaxial pedicle screws are made of Ti6Al4V titanium alloy compliant with ISO 5832-3 and are available in 5.0 mm, 6.0 mm, 7.0 mm, and 8.0 mm diameters. The screws range in length from 35 to 60 mm.

The system includes both straight and pre-bent rods made of Ti6Al4V titanium alloy.

The transverse connectors are composed of Ti6Al4V titanium alloy compliant with ISO 5832-3. These connectors are used to build a transverse connection between two union rods.

The hooks are made of Ti6Al4V titanium alloy and are provided in multiple configurations.

The purpose of this 510(k) is to extend the ISS line to include:

- New monoaxial and polyaxial screws
- Cobalt Chromium rods
- New Ti6Al4V titanium alloy rods
- Offset connector and associated offset connector screws
- Rod to rod connectors
- New instruments

The IMPLANET Spine System has principles of operation substantially similar to other pedicle screw-based systems for the indications listed.

The IMPLANET Spine System components may be used for posterior pedicle screw fixation in pediatric cases: polyaxial and monoaxial screws, rods, transverse connectors and rods. The purpose of the subject 510(k) notice is for a line extension to incorporate additional device dimensions and Cobalt Chromium rods, as well as compatible additional instruments, to the company's cleared system.

Technological Characteristics

The IMPLANET Spine System is composed of smooth fusion rods, pedicle screws, bolts, rod to rod and transverse connectors offset connector and associated offset connector screws, and spinal hooks.

Performance Data

The modified IMPLANET Spine System was tested to the following performance standards:

- Static axial gripping capacity, static flexion/extension bending, static axial torque gripping capacity – ASTM F1798;
- Static compression bending – ASTM F1717;
- Static torsion – ASTM F1717;
- Dynamic compression bending – ASTM F1717;
- Cytotoxicity – ISO 10993-5;
- Acute systemic toxicity – ISO 10993-11.

All results confirmed that the modifications to the device described in this submission do not adversely impact mechanical strength compared to the predicate. In addition, the device is biocompatible.

Substantial Equivalence

The ISS has the same intended use and similar indications, principles of operation, and technological characteristics as the predicate device. The minor differences in the modified device's technological characteristics, namely a line extension to incorporate additional device dimensions and Cobalt Chromium rods as well as compatible additional instruments, do not raise any new questions of safety or effectiveness. Performance data demonstrates that the ISS is substantially equivalent to its predicate device.

Conclusions

The modified ISS is substantially equivalent to the predicate, ISS system.